**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-567/S-016

Bristol-Myers Squibb Company
Attention: Lisa Percival, Associate Director
Global Regulatory Strategy
5 Research Parkway
Signature 91 Bldg.-3SIG-515
Wallingford, CT 06492

Dear Ms. Percival:

Please refer to your supplemental new drug application dated October 4 2007, received October 4, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for REYETAZ® (atazanavir sulfate) capsules, 100 mg, 150 mg, 200 mg and 300 mg.

We acknowledge receipt of your submissions dated April 3, 2008, June 3, 2008, July 2, 2008, July 24, 2008 and August 1, 2008.

This supplemental new drug application provides for the revision of the U.S. package insert to include clinical drug-drug interaction information regarding the administration of REYETAZ® with or without ritonavir (RTV) and hormonal contraceptives, nevirapine, efavirenz, triazolam, orally administered midazolam, parenterally administered midazolam, H2-Receptor antagonists and drugs that are substrates of cytochrome p450 2C8.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert and patient package insert) submitted on August 1, 2008.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-567/S-016**". Approval of this submission by FDA is not required before the labeling is used.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text/submitted labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

In addition, within 21 days of the date of this letter, amend any pending applications for REYETAZ® (NDA 21-567/S-017) with content of labeling in structured product labeling (SPL) format to include the changes approved in these applications.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kwadwo (Kojo) Awuah, Pharm.D, Regulatory Project Manager, at (301) 796-0608.

Sincerely,

*{See appended electronic signature page}*

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosures: Package Insert (PI)
Patient Package Insert (PPI)

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Jeffrey Murray

8/15/2008 02:43:12 PM